

Non-CBI Cover Letter

November 19, 2021

Via Email and Via First Class Mail

Ethylene Oxide Commercial Sterilization Section 114 ICR Response
U.S. EPA Office of Air Quality Planning and Standards
Sector Policies and Programs Division, Fuels and Incineration Group
Mail Code E143-05
109 T.W. Alexander Drive
Research Triangle Park, NC 27711

Re: Terumo BCT Sterilization Services Inc.'s Response to Ethylene Oxide Commercial
Sterilization Section 114 Information Collection Request

Dear Ms. Spells:

I write on behalf of Terumo BCT Sterilization Services Inc. ("Terumo BCT Sterilization") in response to the U.S. Environmental Protection Agency's ("EPA") September 13, 2021 Clean Air Act ("CAA") Section 114 Information Collection Request ("ICR") concerning emissions at ethylene oxide ("EtO") commercial sterilization facilities. Terumo BCT Sterilization is a wholly owned subsidiary of Terumo BCT, Inc., the addressee of EPA's ICR. This response is one of two submissions concerning the Terumo BCT Sterilization Lakewood, CO facility. The other response contains Confidential Business Information ("CBI"); this response does not.

As requested, our responses are included in the specific Excel Workbooks. With respect to our responses, Terumo BCT Sterilization makes the following general qualifications and objections to the ICR:

1. Terumo BCT Sterilization objects to the ICR to the extent it seeks privileged information, including all communications and documents that are protected from disclosure by the attorney client privilege, the work product doctrine, or other applicable privileges.
2. Terumo BCT Sterilization objects to the ICR to the extent it seeks information or documents not within Terumo BCT Sterilization's possession, custody, or control. All responses are made on behalf of Terumo BCT Sterilization.

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3. Terumo BCT Sterilization conducted a good faith review of its relevant documents to prepare the enclosed responses. However, Terumo BCT Sterilization did not search for every document or piece of information that may exist in the possession, custody, or control of any of Terumo BCT Sterilization's employees and agents where any such items are not included within the results of a reasonable search of records maintained in the ordinary course of business. This response is not intended as an admission or a representation that additional information or documents do not exist.

4. As a response to our email request to Ms. Charlene Spells, Office of Air and Radiation, dated 17 November 2021, Ms. Spells confirmed Terumo BCT Sterilization is not required to have a Professional Engineer or Certified Industrial Hygienist certify the responses in the enclosed Excel Workbooks.

5. Terumo BCT Sterilization reserves the right to modify, amend, or supplement its responses, which are made based on the current status of its knowledge, understanding, belief, and searches for information and documents.

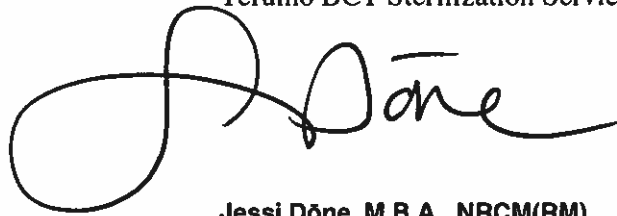
Accordingly, subject to these qualifications and objections, Terumo BCT Sterilization provides the following Excel Workbooks with responses on an encrypted thumb drive (password sent via email):

Terumo BCT Sterilization_LakewoodCO_EtO_114ICR_Main_NonCBI

Please confirm receipt of this submission by emailing me at Jessi.Done@terumobct.com. Feel free to contact me by phone (303-205-2601) or email if you have any questions or need any additional information.

Sincerely,

Terumo BCT Sterilization Services, Inc.

A handwritten signature in black ink, appearing to read "Jessi Done", with a large, stylized loop at the beginning.

Jessi Done, M.B.A., NRCM(RM)

Vice President and Senior Plant Manager